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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,556	12/13/2005	Sushil K Dubey	4062-167	5359

23117 7590 05/03/2007  
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ARLINGTON, VA 22203

EXAMINER
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DAVIS, BRIAN J

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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05/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,556	<b>Applicant(s)</b> DUBEY ET AL.	
	<b>Examiner</b> Brian J. Davis	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 1-11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/24/05</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The lined-through entries of the 6/24/05 IDS fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The information referred to therein has, therefore, not been considered.

### ***Specification***

The disclosure is objected to because of the following informalities: the disclosure contains numerous instances of non-standard (or informal) English grammar as well as obvious spelling errors, for instance, page 2, line 11: "It is evident from [the] above that [al]though [the] prior art looks conceptually very good, *but* it is very cumbersome & time consuming." Additionally, as a matter of style, the substitution of the & symbol for the word *and* is an informal usage and should be avoided. Appropriate correction is required.

### ***Claim Objections***

Claims 1-11 are objected to because of the following informalities: as was noted above for the specification, the claims also contain numerous instances of non-standard English grammar as well as obvious spelling errors, for instance, in claim 1: "...a

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suitable disaster[e]omeric salt[s]...solubility properties [are] exploited...temperature range [to] obtain [the] desired...". Analysis of the remaining claims is similar. Also, as above, with particular reference to claim 7, substitution of the & symbol for the word *and* is an informal usage and should be avoided. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how *resolving* [emphasis added] (R,S)-5-(2-aminopropyl)-2-methoxybenzenesulfonamide with tartaric acid forms a *mixture* of diastereomeric salts. That is, resolution, by definition, should separate such a mixture, not yield one. The term "suitable" is indefinite because it is undefined. Likewise, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Use of this phrase is particularly confusing in the instant claim since the full phrase ("...such as herein (before) described...") appears to refer to the specification, and it is settled case law that references to the specification are improper except in rare instances. *Ex parte Fressola*, 27 USPQ 2d 1608 (USPTO Bd. of App. & Int. 1993). The exact nature of the steps of the process are also unclear due to the

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reference made to *the* [emphasis added] polar and alcoholic solvents at the end of the claim text - when no prior recitation or reference exists to such solvents.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The exact meanings of the term "coupled" and the phrase "varying ratios" are unclear because they are undefined. Likewise, the phrase "such as" or the word "like" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948);

and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the claim implicitly recites the broad recitation “all temperatures,” and the claim also recites “preferably...at...60-65°C) which is the narrower statement of the range/limitation.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is insufficient antecedent basis of for the limitations “first stage operations,” “second stage operations,” and “second stage mother liquor.” The examiner respectfully suggests that these claims should properly depend from claim 3. In addition, the exact meaning of the term “operations” is unclear because it is undefined.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps of the process whereby racemic (R,S)-5-(2-amimopropyl)-2-methoxybenzenesulfonamide is prepared from 5-acetonyl-2-methoxybenzenesulfonamide. A claim referring to the specification (“...as shown in scheme: 2...””) is improper except in rare instances. *Ex parte Fressola*, 27 USPQ 2d 1608 (USPTO Bd. of App. & Int. 1993). The process is also unclear because although the claim refers to the preparation of racemic (R,S)-5-(2-amimopropyl)-2-methoxybenzenesulfonamide, scheme 2 clearly is a method for preparing one enantiomer in particular – not a racemic mixture.

The remaining claims are also rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite. *Ex parte Cordova*, 10 USPQ 2d 1949, 1952 (PTO Bd. App. 1989).

### ***Allowable Subject Matter***

The subject matter of claims 1-10 would be allowable once the objections and 112 rejections outlined above have been overcome. The following is a statement of reasons for the indication of allowable subject matter:

The closest prior art appears to be EP 257787, cited by applicant in the IDS, which teaches a process for the preparation of (R)-(-)-5-(2-aminopropyl)-2-methoxybenzenesulfonamide by reacting 5-acetonyl-2-methoxybenzenesulfonamide with an optically active benzylic amine. The resulting compound is then resolved and debenzylated to yield the desired product (page 6, line 6). The cited prior art neither teaches nor suggests the instant resolution process starting from racemic 5-(2-aminopropyl)-2-methoxybenzenesulfonamide and its resolution using tartaric acid.

At best, it might have been obvious to try resolving the racemic mixture (as opposed to a mixture of its derivative) using a simple optically active acid such as tartaric acid, however, an 'obvious to try' standard is impermissible in two situations: 1) where the prior art gives no indication as to which of numerous parameters are critical, or gives no indication as to which of many possible choices is likely to be successful; and 2) where the prior art gives only general guidance with respect to the form of the invention but not how to achieve it new areas of technology or in fields of

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experimentation which are only seemingly promising. *In re O'Farrell*, 853 F2d 894, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988). In the instant case, 1 above applies.

The cited prior art neither teaches nor suggests the instant process. Nor would it have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of the prior art in order to arrive at those of the instant invention. There is no motivation to do so.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**BRIAN DAVIS**  
**PRIMARY EXAMINER**

Brian J. Davis  
April 29, 2007